K121703
1 of 4

DEC 7 2012

510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

I. Sponsor's Information

Name:	**Medi-Khan USA, Inc.**
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Official Correspondent:	Kachi Enyinna, Principal Consultant 510K Technology Group, LLC 399 Massachusetts Avenue, Suite 2 Boston, MA 02115 (240) 994-4242
Establishment Reg. No.:	3007134825
Date Prepared:	June 8, 2012

II. Device Name

Trade Name:	Lipokit with disposable 50cc AFT Syringe, model LK-101
Common Name:	Suction Lipoplasty System
Classification Name:	System, Suction, Lipoplasty
Classification Number:	878.5040
Product Code:	MUU
Classification Panel:	General and Plastic Surgery

III. Predicate Device

Lipokit with disposable 50cc AFT Syringe (K083455)

IV. Indications for Use

The Lipokit is used in the tumescent injection, aspiration, harvesting, filtering and transferring of autologous fat tissue.

The Lipokit is intended for use in the following surgical specialities when the aspiration of soft tissue is desired:

- Plastic and Reconstructive Surgery
- General Surgery
- Dermatological Surgery
- Obstetrician & Gynecological Surgery
- Cosmetic Surgery

The Lipokit is indicated for use when harvesting of highly concentrated pure fatty tissues for aesthetic body and facial contouring is desired.

V. Device Description

Design Characteristics
The Lipokit with disposable 50cc AFT Syringe is composed of one centrifuge unit with a motor for suction and positive pressure; a 50cc AFT (autologous fat transfer) syringe with weight-mesh piston, a cannula and other ancillary parts. The vacuum and positive pressure are controlled using a foot pedal control switch.

The Lipokit is a sterile, single-use, manual device consisting of a cannula, and tissue collection container (the 50cc AFT Syringe) that relies on the centrifuge unit for its energy supply. The cannula is attached directly to the 50cc AFT Syringe which simplifies and reduces the steps needed in the collection, filtering and transfer of the autologous fat. In so doing, the harvested fat is less traumatized and risk of contamination is lowered because the fat never leaves the harvesting syringe until re-injection. The cannula is a hollow tube with an opening near the tip to communicate the centrifuge unit to the tissues and subsequently aspirate, harvest and filter subcutaneous fatty tissues from the patient into the collection container (the 50cc AFT Syringe).

The stainless steel cannula that contacts the patient is provided a various sizes ranging from 2.5 – 4.0mm in diameter. The tip region of the cannula may have a single or multiple openings that range in size from 170mm to 260mm in length distributed uniformly or randomly though the end of the cannula.

The 50cc AFT Syringe is a polymeric 50cc volume luer-lock style, single-use syringe consisting of a polypropylene barrel with printed graduations and a weight-mesh piston composed of polycarbonate.

Material Composition
No change in material composition. The components of Lipokit that have direct patient contact are fabricated from surgical stainless steel.

Sterility
Sterility requirements as approved in the original device has not changed for the modified device. The 50cc AFT Syringe is sterilized by ethylene oxide (EtO) gas.

Design and Materials
The design and materials of the modified Lipokit with disposable 50cc AFT Syringe remains the same as the legally cleared Lipokit with disposable 50cc AFT Syringe. The only change to the design of the cleared Lipokit is the addition of a transformer to step down the voltage input of the Lipokit from 220V/60Hz to 120V/60Hz. The engery source has not been modified and remains the same as the cleared Lipokit. Other than the change in voltage input requirement for the Lipokit, there are no other changes to the design, material, intended use or fundamental scientific technology.

Technological Characteristics
There are no changes in the technological characteristics to the previously cleared Lipokit with disposable 50cc AFT Syringe. The Lipokit with disposable 50cc AFT Syringe incorporates changes pertaining only to the addition of the transformer to step down the voltage of the Lipokit from 220V/60Hz to 120V/60Hz for use in U.S. market. There were no hardware changes made in the machine to accommodate this modification. The following technical specifications of the modified device remain the same as the unmodified device:

- Safety System
- System performance
- Environmental requirements
- Transportation and Storage condition
- User Interface
- Hardware
- Accessories
- Alarms
- Accuracy and Controls
- Protection against Mechnical Hazard
- Protection against Electrical Hazard
- Protection against excessive temperature or other hazards
- Manufacturing Location and manufacturing processes (assembly, fabrication, testing, shipping, installation and service).

VI. Performance Data

Based on the Risk Analysis, the modified Lipokit was tested for electrical safety and electromagenetic compatiblity in accordance to IEC 60601-1:1998, Am1:91, Am2:95 and

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and tests (Edition 3).

VII. Equivalence to Market Product

The modified Lipokit with disposable 50cc AFT Syringe has the same indicated use, same operating principle, same design, same materials, shelf life and is packaged and sterilized using the same material and processes as the cleared Lipokit (K083455).

In summary, the modified Lipokit described in this submission are, in our opinion, substantially equivalent to the cleared Lipokit with disposable 50cc AFT Syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Medi-Khan USA, Inc.
% 510K Technology Group, LLC
Mr. Kachi Enyinna
399 Massachusetts Avenue, #2
Boston, Massachusetts 02115

December 7, 2012

Re: K121703
Trade/Device Name: Lipokit with disposable 50cc AFT Syringe
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: November 15, 2012
Received: November 20, 2012

Dear Mr. Enyinna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121703

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121703